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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,692	06/01/2001	Christopher C. Andrews	ACS-54593	2493

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EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/872,692	Applicant(s) ANDREWS ET AL.	
	Examiner Kathryn Odland	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 5, 8, 9 and 15-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/16/02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 27-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 1, 2004.
2. Applicant's election without traverse of Species I in the reply filed on June 1, 2004 is acknowledged. Therefore claims 5, 8, 9, and 15-26 are also withdrawn from consideration.
3. Therefore, claims 1-4 6, 7 and 10-14 are under consideration

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Since there are many delivery and recovery systems, a more descriptive title is requested.
5. The disclosure is objected to because of the following informalities: on page 11, the description, of figure 18, states, "FIG. 18 is a similar view of the **third form** of the recovery version of the first embodiment seen in FIG. 16..." However, in the description of FIG. 16, it states that it is the second form.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
7. Claim 7 recites the limitation "the recovery system" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 3, 4 and 7 are rejected under 35 U.S.C. 102(a and/or e) as being anticipated by Daniel et al. in US Patent No. 6,171,327.

Regarding claim 1, Daniel et al. disclose a system for enabling at least one operator to control the delivery of an embolic protection device to a position in a patient's vasculature distal to an interventional procedure site for deployment of the embolic protection device, to enable the operator to control the removal of the delivery system from the patient's vasculature for the exchange of the delivery system, and to enable control of the position of a deployed embolic protection device within the patient's vasculature during an exchange of interventional devices, as stated in the abstract with the phrase "single operator exchange." The device has a guide wire (such as 26), including a distal end, adapted to be positioned within the blood vessel and to extend to a position distal to the interventional procedure site, and to include an embolic protection device (such as 21, etc.) mounted on the distal end thereof; and a catheter (118), including a distal end, wherein the catheter has a lumen therein extending in the catheter to the distal end thereof, and wherein the guide wire and the embolic protection device are adapted to extend in and through

Art Unit: 3743

the lumen, the catheter and the guide wire are adapted to enable the embolic protection device to be delivered and deployed distal to the interventional procedure site, and the catheter includes a manipulation-enabling element (such as 144) for enabling at least one operator to manipulate the guide wire and the catheter independently so as to enable removal of the catheter from the patient's vasculature, as recited in columns 3-4 and column 6, lines 50-67.

Regarding claim 3, Daniel et al. disclose that as applied to claim 1 as well as a catheter that includes a tip, at the distal end thereof, adapted to be shapeable by the operator, to enable the operator to direct the shapeable tip for movement thereof in the patient's vasculature, as discussed throughout the disclosure and seen in numerous embodiments.

Regarding claim 4, Daniel et al. disclose that as applied to claim 1 as well as a system for enabling the at least one operator to control the recovery of the embolic protection device, from the delivered and deployed position thereof, for the exchange of the recovery system, as recited in the abstract and column 6, lines 60-67.

Regarding claim 7, Daniel et al. disclose that as applied to claim 4 as well as a recovery system that includes the catheter, and the distal end of the catheter includes a tip, adapted to be shapeable by the operator, to enable the operator to direct the shapeable tip for movement thereof in the patient's vasculature, and wherein the shapeable tip is further adapted to be expandable to enable the capture

Art Unit: 3743

of the embolic protection device, as discussed throughout the disclosure and seen in numerous embodiments.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 2, 6 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. in US Patent No. 6,171,327.

Regarding claim 2, Daniel et al. disclose that as applied to claim 1. However, Daniel et al. do not explicitly recite a catheter that further includes a mandrel extending therein, adapted to support the catheter, to enable the catheter to maintain a clinically acceptable profile and flexibility during delivery and removal thereof through the patient's vasculature. On the other hand, Daniel et al. recite in column 4, lines 10-13 that the catheter "should be made from a material sufficiently rigid, yet flexible to be advanced through a tortuous path to the target site." Therefore, although not explicitly recited a mandrel would be obvious to one with ordinary skill

Art Unit: 3743

in the art and within the scope of the invention in order to accomplish the function of maintaining flexibility as well as rigidity.

Regarding claim 6, Daniel et al. as modified disclose that as applied to claim 2 as well as a catheter that includes a distal end portion, extending from the distal end to a location spaced from the distal end, a proximal end, and a distal-proximal portion, extending from the distal end portion to the proximal end, and the manipulation-enabling element (144) that extends along the distal-proximal portion of the catheter, as recited in column 6, lines 50-67.

Regarding claim 10, Daniel et al. as modified disclose that as applied to claim 6 as well as a manipulation-enabling element (such as 144) that is adapted to enable the guide wire to be peeled away from and extend outside the catheter and along the distal-proximal portion thereof, as recited in column 6, lines 50-67.

Regarding claim 11, Daniel et al. as modified disclose that as applied to claim 6 as well as a manipulation-enabling element (such as 144) that is a slit extending along the distal-proximal portion of the catheter, as recited in column 6, lines 50-67.

Regarding claim 12, Daniel et al. as modified disclose that as applied to claim 10 as well as a manipulation-enabling element that is adapted to enable a minor portion of the guide wire to extend in the lumen, and a major portion of the guide wire to extend outside the catheter therethrough, as recited in column 6, lines 50-67.

Art Unit: 3743

Regarding claim 13, Daniel et al. as modified disclose that as applied to claim 11 as well as a slit that is adapted to enable the catheter and the guide wire to be manipulated by the operator, so as to enable the guide wire to exit from and extend therethrough, and outside and along the distal-proximal portion of the catheter, as recited in column 6, lines 50-67.

Regarding claim 14, Daniel et al. as modified disclose that as applied to claim 13 as well as a catheter proximally- extending portion further includes a port therein proximate the distal end portion of the catheter, for enabling the guide wire to exit therefrom and extend therethrough, outside and along the distal-proximal portion of the catheter, as recited in column 3, lines 58-63.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2004/0054347; US 2002/0133217; US 2002/0052626; US 2002/0035347; US 2002/0022858; US 2001/0029362 and US Patent No. 6,537,294.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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